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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,845	09/18/2001	Johnathan A. Napier	05407.00003	1445

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,845	NAPIER, JOHNATHAN A.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,35 and 37* is/are pending in the application.

4a) Of the above claim(s) *16-34,36 and 38-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-15,35 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1652.

2. ***Election***

Applicant's election of Group I, claims 1-15, 35 and 37 in Papers filed December 12, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. **Claims withdrawn** :

Claims 16-34, 36 & 38-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Claims 1-15, 35 and 37 are under consideration in this examination.

5. ***Priority***

Acknowledgment is made of applicants' claim for priority based on an applications filed in United Kingdom on March 18, 1999 & February 18, 2000.

6. ***Abstract***

*This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

*The abstract should be in narrative form and generally limited to a single paragraph within the range of 50 to 150 words [in length since the space provided for the abstract on the computer tape by the printer is limited]. The form and legal

phraseology often used in patent claims, such as "means" and "said", should be avoided in the abstract. The abstract should sufficiently describe the disclosure to assist readers in deciding whether there is a need for consulting the full patent text for details. MPEP 608.01(b).

7. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. ***Enablement***

Claim 1-15, 35 & 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide sequence of SEQ ID NO: 15 having long chain polyunsaturated fatty acid (PUFA) elongase activity for extending the chain length of an 18 carbon PUFA to 20 carbons, does not reasonably provide enablement for : (1) any PUFA elongase from any source or any eukaryote, and/or (2) any PUFA elongase having 60%, 80% 90% homology to SEQ ID NO: 15 or any variant of SEQ ID NO: 15.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988))[*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation

necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim. The factors most relevant to this rejection are [the scope of the claims, unpredictability in the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

The specification provides guidance and examples for making an isolated polypeptide comprising the sequence of SEQ ID NO: 15 and the encoding DNA of SEQ ID NO: 7. However, the specification does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. The state of the art as exemplified by Attwood et al. [Comput. Chem. 2001, col. 54(4), pp. 329-39] is such that "..we do not fully understand the rules of protein folding, so we cannot predict protein structure; and we cannot invariably diagnose protein function, given the knowledge only of its sequence or structure in isolation" (see abstract and the entire publication). Further Ponting [Brief. Bioinform. March 2001, Vol. 2(1), pp. 19-29] states that "...predicting function by homology is a qualitative, rather than quantitative process and requires particular care to be taken, due attention should be paid to all available clues to function, including orthologue identification, conservation of particular residue types, and the co-occurrence of domain in proteins" (see abstract and the entire publication).

The standard of meeting enablement requirement is whether one of skill in the art can make the invention without undue experimentation. The amount of experimentation

to make the claimed polypeptide is enormous and entails selecting specific nucleotides to change (deletion, insertion, substitution or combination thereof) in a polynucleotide (or DNA) to make a claimed polypeptide and determining by assays whether the polypeptide has activity. The specification does not provide guidance with respect to the specific structural/catalytic amino acids and the structural motifs essential for enzyme structure/function which must be preserved. Thus, searching for the specific nucleotides to change (deletion, insertion, substitution or combination thereof) in a polynucleotide to make polypeptide that is a variant to any degree, or is at least 60%, 80% or 90% identical to a polypeptide comprising sequence of SEQ ID NO: 15 is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no structural motifs essential for enzyme structure and activity/function which must be preserved.

Further, no guidance is provided regarding the occurrence or isolation of the specific elongase from sources other than *Caenorhabditis elegans*. The prior art (see instant specification, page 2, last paragraph through page 3, 1st paragraph) cited in the specification disclose genes encoding elongases from yeast and plants with no detectable homology among them. Therefore, based upon the sequence of *C. elegans* [SEQ ID NO: 15], it would be impossible for one skilled in the art, to detect elongases from any source.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding elongases from diverse sources, as well as the specific catalytic amino acids and structural motifs essential for activity/function which must be

preserved, in order to modify the elongase sequence to any extent. Without such a guidance, the experimentation left to those skilled in the art is undue.

9. Accession No. Q03574 [created 02.01.1994], from *C. elegans* cited in Applicant's Information disclosure Statement, is 100% identical to Applicant's SEQ ID NO: 15, is disclosed as a integral membrane protein having a similarity to ELO family, is not used in any prior art rejection(s), because of insufficient basis or motivation to equate or make obvious the functionality assigned to instantly claimed elongase of SEQ ID NO: 15.

10. ***Pharmaceutical composition***

Claims 35 & 37 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for an isolated polypeptide sequence of SEQ ID NO: 15 having long chain polyunsaturated fatty acid (PUFA) elongase activity for extending the chain length of an 18 carbon PUFA to 20 carbons.

Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988) [*Ex parte* Forman [230 USPQ 546 (Bd. Pat. App. & Int. 1986)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

It is neither taught nor any data is provided for using the elongase of SEQ ID NO : 15 in pharmaceutical compositions for the treatment of any of the diseases or

disorders. There is no evidence presented that elongase of SEQ ID NO : 15 is associated with any of the known diseases or disorders or can be treated by administering the enzyme. Without such a data or evidence, claims to pharmaceutical composition comprising enzyme, would amount to a composition or potential drug for treatment for any disorder or disease, which is not enabled. Given the lack of direction or guidance and the nature of the invention, obtaining such a composition for one of skill in the art would be highly unpredictable. This is because the elongase of SEQ ID NO : 15 when associated with a particular disease or disorder would be expressed differentially. Manipulating or controlling these levels depends upon the disease or disorder, and may not always be controlled by supplementing with such an enzyme composition. Further, no guidance in provided, pertaining to the fate of the administrated elongase in vivo.

Since it is not routine in the art to engage in *de novo* experimentation to prepare numerous compositions where the expectation "of success is unpredictable", the skilled artisan would require additional guidance, specific to individual disorder or disease, in order to make and use pharmaceutical compositions in a manner reasonably commensurate with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

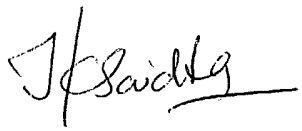
Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by USP 6,403,349 [Mukerji et al., filing date September 2, 1998]. Mukerji et al. teach genes involved in the elongation of polyunsaturated fatty acids (i.e., "elongase") and uses thereof. In particular, elongase from *C. elegans* among other species is taught which converts gamma linolenic acid (GLA, 18 carbon) to dihomogamma linolenic acid (DGLA, 20 carbon) and converts 20:4n-3 to eicosapentaenoic acid (EPA). See abstract, for example. Mukerji's elongase [see SEQ ID NO: 11] is about 31% identical to Applicants' SEQ ID NO: 15, however, functionally similar, therefore, anticipates the claims.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (571) 272-0940. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group in the Technology Center is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is 571 272-1600.



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June 22, 2004